DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 7, 2014

Mr. Garrett P. Ahlborg
Senior Regulatory Affairs Specialist
c/o Entellus Medical, Inc.
3600 Holly Lane North
Plymouth, MN 55447

Re: K141916
Trade/Device Name: Pathassist led light fiber
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, and Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: July 14, 2014
Received: July 15, 2014

Dear Mr. Ahlborg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K141916

Indications for Use

Applicant: **Entellus Medical, Inc.**

510(k) Number (if known): _____

Device Name: PathAssist LED Light Fiber

Indications for Use

To locate, illuminate within, and transilluminate across nasal and sinus structures in patients aged 18 and over.

Prescription Use____X_____- (21 CFR 801 Subpart D) OR/AND Over-the-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH Office of Device Evaluation (ODE)

Vasant G. Malshet -S

510(k) Summary

Date Prepared: July 14, 2014

Submitter Information:
Entellus Medical, Inc.
3600 Holly Lane North, Suite 40
Plymouth, MN 55447

Establishment Registration: 3006345872

Contact Information:
Garrett P. Ahlborg
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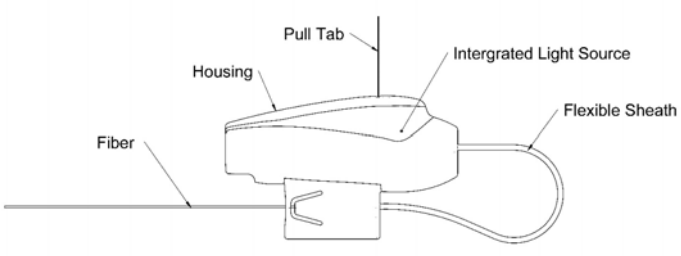
Device Information:

- **Trade Name:** PathAssist LED Light Fiber
- **Common Name:** Sinus Guidewire
- **Classification Name:** ENT Manual Surgical Instrument
- **Product Code:** LRC
- **Regulation Number:** Class I, 21 CFR 874.4420

Predicate Device: PathAssist LED Light Fiber [K130503]

Device Description:
The PathAssist LED Light Fiber is a flexible instrument that emits light from the distal end. The LED Light Fiber is provided sterile and is for single use only. The device consists of a flexible illumination fiber, a protective sheath and an integrated battery powered LED light source. When the LED Light Fiber is activated the fiber will emit red light from the distal tip for over 60 minutes. It has a fiber nominal working length of 27.6cm with an outer diameter of 0.375mm (0.015").

The PathAssist LED Light Fiber is packaged alone or may be packaged with XprESS (LoProfile suction tip).



PathAssist LED Light Fiber

Indication for Use
To locate, illuminate within, and transilluminate across nasal and sinus structures in patients aged 18 and over.

Contraindications:
None

Technological Characteristics:
The subject device has the same indications for use and fundamental scientific technology as the predicate device [K130503]. The subject device has the same technological characteristics (i.e., principle of operation, basic design, function, basic materials, biocompatibility, packaging, shelf life and sterilization) as the predicate device.

Substantial Equivalence:
The subject device has the same indications for use and fundamental scientific technology as the predicate device. The LED Light Fiber is substantially equivalent to the predicate device.

Performance Data:
Performance testing of the PathAssist LED Light Fiber consisted of design verification testing to support the device modifications. Design verification testing included functional, mechanical, compatibility, and thermal safety testing. Packaging testing, sterilization, shelf life, EMC and electrical safety testing, biocompatibility, animal and clinical data were not submitted. Performance testing showed that the device meets design specifications and performed as intended.

Conclusion
In conclusion, the indications for use and technological characteristics are the same as or equivalent to the predicate device. Performance testing has demonstrated that the device is safe and effective and that its performance is substantially equivalent to the predicate device.